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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/767,646 | 01/29/2004 | Roger P. Jackson | 10,390 | 5706 |
| <div>7590 John C. McMahon PO Box 30069 Kansas City, MO 64112</div> | | | <div>EXAMINER WOO, JULIAN W</div> | |
| | | | <div>ART UNIT 3731</div> | <div>PAPER NUMBER</div> |
| | | | <div>MAIL DATE 06/12/2007</div> | <div>DELIVERY MODE PAPER</div> |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/767,646 | Applicant(s) JACKSON, ROGER P. | |
| | Examiner Julian W. Woo | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1, 5, 6, and 11 are objected to because of the following informalities.

With respect to claim 1, line 11, after "top," --surface-- should be inserted. With respect to claims 5, 6, and 11: Each of these claims is dependent upon claim 4, which is a cancelled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 8, "said plug" lacks antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Dent (GB2140523). With respect to claim 14, Dent discloses, at least in figures 9 and 14-16, a plug closure including a closure (14A) having at least a pair of bores (20) each positioned in spaced relationship to both an axis of the closure and to a periphery of the

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closure, the bores being in parallel to the axis and being accessible from a top of the closure; and a break-off head (14B) attached to the top of the closure and breakable therefrom upon application of a preselected torque to the break-off head, the break-off head being free of bores providing axial access the bores, and the bores being positioned so as to be inaccessible by a removal tool until the break-off head is broken from the closure. With respect to claim 15, Dent discloses a closure including a closure body (14B) that is cylindrical with a radially outward surface that has a thread thereon (at 12), where the body has a pair of spaced bores (20) that are spaced radially outward from the axis of rotation, are generally parallel to the axis of rotation, and intersect with an upper surface of the body (at 18). Note: The introductory statements of intended use (e.g., "for use with an open-headed medical implant having a pair of spaced and interiorly threaded arms") have been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Dent's device, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3, 5, 6, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schilder (EP0276153) in view of Grunbichler (5,713,705), and further in view of Johnson (1,300,275). Schilder discloses, at least in the figure and in col. 3, lines 22-26 and lines 57-61; the invention substantially as claimed. Schilder discloses a closure plug usable in an open-headed medical implant having a pair of spaced and interiorly threaded arms, where the plug includes a body with a radially outward surface with a thread thereon (at 5); top and bottom surfaces, where the top has two bores (4) sized and shaped to receive a tool and extending generally axially at least partially through the body from top to bottom thereof, where each bore is spaced from a central axis of the body, where the plug includes a break-off head (1) attached to the body and being breakable from the body at a preselected torque; the break-off head being positioned so as to be axially located above the body and being free of pass-through openings; where the body is generally cylindrical in shape, where the body includes a neck (2) positioned between the bores, where the break-off head has a tool-grippable (hexagonal) outer surface, and where the plug includes a tool having a grippable handle and an engagement face including a post extending parallel to an axis of rotation of the tool for each body bore (i.e., a "removal aid" with "two projecting pins" or a "box spanner" with "pins"). However, Schilder does not disclose that the break-off head is not axially located above at least a portion of a bore, nor does Schilder disclose that a

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bore is spaced from and positioned between both the central axis and a periphery of the body. Grunbichler teaches, at least in figures 1-11B and in col. 3, lines 10-14 and col. 4, line 66 to col. 5, line 8; a break-off head (3) that is positioned axially above a plug body, so that it axially blocks an entire top surface of the plug body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Grunbichler, to modify the break-off head, so that it is axially located above at least a portion of a bore (i.e., such that the break-off head axially blocks substantially an entire top surface of a plug body). Such a break-off head would accommodate the application of conventional and readily available tools for the application of torque to the break-off head (e.g., wrench, ratchet nut, Allen wrench, or screwdriver), where the choices of a tool to be applied and a break-off head would be dependent upon the size and configuration of the plug and the confines of a surgical site as well as the preferences of a surgeon.

Moreover, Johnson teaches, at least in figure 4 and in lines 70-102; a plug with a bore spaced from and positioned between both the central axis and a periphery of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the plug of Schilder (or Schilder in view of Grunbichler), so that the bore is spaced from and positioned between both the central axis and a periphery of the body. Such a bore configuration and position would allow the plug body to receive an entire circumference of a pin of the tool and allow the tool to hold the plug during turning and removal of the plug.

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8. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schluder (EP0276153) in view of Grunbichler (5,713,705) and Johnson (1,300,275), and further in view of Wagner (5,334,203). Schluder in view of Grunbichler and Johnson discloses the invention substantially as claimed, but does not disclose three spaced tool receiving bores being spaced 120 deg. from adjacent tool receiving bores. Wagner teaches, at least in figure 1, a closure plug (38) including three spaced tool receiving bores being spaced 120 deg. from adjacent tool receiving bores. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wagner, to modify the device of Schluder in view of Grunbichler and Johnson, so that there are three spaced tool receiving bores being spaced 120 deg. from adjacent tool receiving bores. Such a configuration of bores (and a tool as taught by Wagner) would allow the tool to grip a closure plug and exert more torque for turning the plug and ease its installation or removal.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable Schluder in view of Grunbichler and Johnson, and further in view of Parker et al. (6,053,078). Schluder in view of Grunbichler and Johnson discloses the invention substantially as claimed, but does not disclose four spaced tool receiving bores as claimed. Parker et al. teach, at least in figure 2A and in col. 3, lines 36-46 and col. 4, lines 9-11; a plug (10) with at least four spaced tool receiving tool receiving bores as claimed, which are configured to receive a tool (20). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Parker et al., to modify the device of Schluder in view of Grunbichler and Johnson, so that there are four spaced

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tool receiving bores as claimed. Such a configuration of bores would allow the tool to grip the closure plug and transfer more torque for turning the plug and ease its installation or removal.

10. Claims 7, 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schluder in view of Grunbichler and Johnson, and further in view of Reed (6,261,039). Schluder in view of Grunbichler and Johnson discloses the invention substantially as claimed, but does not disclose that the body includes an axial extending bore from the bottom to near the top thereof or a threaded axial extending bore passing entirely through the body from a top to a bottom thereof, where the axial bore is located beneath the neck and is accessible from a top of the body when the break-off head breaks away from the body. Reed teaches, in figures 1-3, 11-13, 15, and 16, a closure plug body (10) including a threaded axial extending bore (114) from the bottom to near the top thereof, where the axial bore is located beneath (and through) a neck (30) and is accessible from a top of the body when a break-off head (20) breaks away from the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Reed, to include a threaded axial extending bore as claimed in the closure plug of Schluder in view of Grunbichler and Johnson. Such a modification would allow the device of Schluder in view of Grunbichler and Johnson to be used in thread repair, where the axial bore is adapted to receive a desired threaded fastener.

Schluder in view of Grunbichler and Johnson also does not disclose a threaded set screw sized and shaped to be received in the axial bore, where the set screw is

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sized and shaped to extend outward from the body bottom surface when the screw is fully installed therein. Reed also teaches a set screw (300) to be received in the axial bore. It would also be obvious to one having ordinary skill in the art at the time the invention was made, to include a set screw in the device of Schluder in view of Grunbichler and Johnson, as modified by Reed. Such a screw would allow the thread of the axial bore to remain clean and retain its integrity during application of torque to the break-off head. Moreover, it would have been obvious to one having ordinary skill in the art to size the screw, so that it extends outward from the body bottom surface when the screw is fully installed therein, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Response to Amendment

11. With respect to claim objections and the rejection under 35 U.S.C. 112, 2nd paragraph: See the new objections and rejection above. Applicant's arguments filed on March 19, 2007 have been fully considered but they are not persuasive with respect to claim 14: As shown in the restated rejection above, Dent indeed discloses a plug closure as claimed. With respect to claim 15: The Applicant did not amend the claim or present arguments regarding the rejection of this claim, which is restated above. Applicant's arguments with respect to claims 1-3 and 5-13 have been fully considered, but are moot in view of the new grounds of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

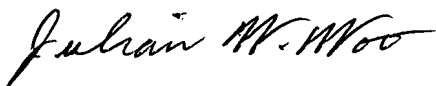
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is fluid and cursive, with the first name "Julian" being more prominent than the last name "Woo".

Julian W. Woo
Primary Examiner

June 5, 2007